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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/320,100	05/26/1999	DEBORAH ANN ANSALDI	P1363R1	4114

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EXAMINER

HUNT, JENNIFER ELIZABETH

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/02/2002 20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/320,100

Applicant(s)
Ansaldi et al.

Examiner
Jennifer Hunt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 20, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5, 17
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Response to Amendment

1. Claims 1-13 are pending in the application.
2. The declaration under 37 CFR 1.132 filed 9-20-2001 is insufficient to overcome the rejections of claims 1-13 set forth in the last Office action for the reasons generally set forth below, and specifically addressed in the arguments throughout this action.

The declaration appears to be drawn to methods of purifying protein monomers from solutions consisting of multimers and/or dimers of the monomer. This is not commensurate in scope with the instant claims which are drawn to methods of separation of monomers from mixtures comprising dimers and/or multimers, but also which may contain other proteins, multimers, dimers, variants, and so forth.

With regard to the "further evidence of unobviousness", the high levels of yield and purity cited by Steven Cramer, Ph.D. as "unexpected" are not commensurate in scope with the claims. The instant application only discloses these results when specific reaction conditions are used for protein purification of homogenous commercial solutions. The claims are drawn generally to separation of any mixture, provided that it contains multimers and dimers. Dr. Steven Cramer, Ph.D.'s conclusions are drawn specifically to methods of purifying homogenous mixtures. Thus the declaration is not commensurate in scope with the claims.

Claim Rejections Maintained

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3. The grounds of rejection of claims 1-2, 5-7, and 9-13 under U.S.C. 102(b) as being anticipated by Yang et al., Journal of Chromatography, A743, 1996 is maintained for reasons of record.

Applicant argues that Yang et al. fails to teach the instantly claimed method because Yang et al. fails to disclose each and every element of the claimed invention, specifically that “monomeric proteins can be purified from dimeric and/or multimeric forms thereof and obtained in a yield and level of purity of such high degree” as that instantly claimed. Applicant alleges that monomers would not inherently be separated from dimers and/or multimers, and that the instant technique would not inherently result in the claimed levels of purity and yield. Applicant submits as support for this argument, a declaration by Steven M. Cramer, Ph.D. Applicant's arguments filed 9-20-2001 have been fully considered but they are not persuasive.

Applicant's arguments and declaration are not commensurate in scope with the claims, as set forth above and further addressed herein. The instant claims are not drawn to a method of purification, but rather to a method of separation. The claims are far more broadly drawn than the instant arguments or declaration would imply. The instantly claimed methods of cation and anion chromatography are well known in the art for protein separation, as set forth above, in previous office actions, and in applicant's arguments and declaration. Further, one of skill in the art would expect that a known method of protein separation, applied to a composition comprising multiple types of proteins (as the instant references teaches) would inherently result in the same levels of yield, purity, since the method steps are identical.

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As set forth in previous office actions, the method of Yang et al. is a protein purification method which is identical to the claimed method. In general, Yang et al. teaches a method of using ion exchange chromatography to purify proteins, and further teaches that this method provides many advantages over other art know protein purification techniques. Specifically, as set forth in the previous office actions, Yang et al. teaches a method of applying a mixture (which includes IgG's, ascites and sera, see abstract and examples 3.6.1 and 3.6.2) to a cation exchange chromatography resin with numerous pH's in the 6-7 range or a anion exchange resin with numerous pH's in the 6-9 range.(pages 173-177). Yang et al. details numerous ion exchange techniques, and tests different aspects of these techniques. Yang et al. also uses the method to separate monomers from a mixture of dimers and multimers (serum and ascites).

Thus since the method of Yang et al. is a method of separating/purifying proteins, and the limitations recited in the instant claims are drawn to a protein separation method, one of skill in the art would expect that the identical protein separation methods would function in identical ways, and thus absent evidence to the contrary, would be effective to purify monomers from dimers and multimers of the monomers, and would result in the same levels of purity. While the declaration submitted by Dr. Steven Cramer Ph.D. states that one of skill in the art would not have expected the cation and anion exchange techniques known in the art for protein separation to be effective for purifying monomers from solutions consisting of dimers and/or multimers, this alleged "unexpected result" encompasses only purification of monomers from solutions consisting of dimers and/or multimers of the monomer, and thus is not commensurate in scope

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with claims which are drawn to protein separation in general, from compositions which comprise monomers, dimers and multimers (and thus may contain any other type of material).

4. The grounds of rejection of claims 1-2, 5-7, and 9-13 under U.S.C. 102(a) as being anticipated by Hahn et al., Chromatography, 795, pages 277-287 (1998) is maintained for reasons of record.

Applicant argues that Hahn et al. is not applicable to the instantly claimed invention because Hahn et al. teaches separation of various proteins from each other, and that there is no evidence in Hahn et al. of separation of monomers from their own dimers or multimers. Applicant generally concludes, citing the declaration of Steven Cramer, Ph.D. that the method taught by Hahn et al. would not inherently function to separate monomers from dimers, and further notes that Hahn et al. obtains mediocre results from purification of IgG from other proteins. Applicant's arguments filed 9-20-2001 have been fully considered but they are not persuasive.

As set forth above, applicant's arguments and declaration are not commensurate in scope with the claims. The instant claims are not drawn to a method of purification, but rather to a method of separation. The claims are far more broadly drawn than the instant arguments or declaration would imply. The instantly claimed methods of cation and anion chromatography are well known in the art for protein separation, as set forth above, in previous office actions, and in applicant's arguments and declaration. Further, one of skill in the art would expect that a known

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method of protein separation, applied to a composition comprising multiple types of proteins (as the instant references teaches) would inherently result in the same levels of yield, purity, since the method steps are identical. While not all separations would result in the claimed yield and purity, identical steps performed on identical mixtures would necessarily yield the same results. It is further noted that numerous examples in the instant application obtained lower yield and purity than that instantly claimed, and thus citing a few examples of lower purity would not necessarily describe the method as a whole.

5. The grounds of rejection of claims 1-2 and 4-13 under 35 U.S.C. 103(a) as being unpatentable over Yang et al., in view of US Patent 4,764,279, Tayot et al is maintained for reasons of record.

Applicant argues that Tayot fails to overcome the deficiencies of Yang et al. and fails to teach separation of a monomer from a mixture of monomers and dimers. Applicant further argues that since Tayot teaches a different purification method, that it teaches away from the instant invention. Applicant's arguments filed 9-20-2001 have been fully considered but they are not persuasive.

Applicant's arguments regarding Yang et al. have been addressed supra. As set forth previously, the mixture of Tayot is blood and thus would contain dimers and multimers inherently. Furthermore, as set forth above, one of skill in the art would reasonably expect that a method useful for purifying proteins which is identical in method steps to the instant method

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would function identically as well, and thus perform the specific purification of monomers from dimers and multimers of the monomer, and would result in the same levels of purity which are instantly claimed. Further, Tayot was set forth only to provide the industrial applicability of purification of albumin and thus could use any of the art known purification techniques to conduct such purification, including those taught in Yang et al.

6. The grounds of rejection of claims 1-3 and 5-13 under 35 U.S.C. 103(a) as being unpatentable over Yang et al and Hahn et al., in view of Oncogene Science catalog 1992, pages 18 and 35 is maintained for reasons of record.

Applicant argues that Oncogene Science fails to overcome the deficiencies of Yang et al. and Hahn et al, and fails to teach separation of a monomer from a mixture of monomers and dimers. Applicant further argues that the Oncogene science antibodies are already purified, and thus would not require the instant purification method. Applicant's arguments filed 9-20-2001 have been fully considered but they are not persuasive.

Applicant's arguments regarding Yang et al., and Hahn et al. have been addressed supra. With regard to applicant's argument that the mixture in Oncogene Science does not contain monomers, the reference is submitted to set forth the desirability of purification of the specific antibodies of claim 3. As set forth in previous office actions, it is not necessary that the claimed invention be expressly suggested by in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested

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to one of ordinary skill in the art. (*In re Keller*, 642 F.2d 413,288 USPQ 871 9ccpa 1981).

Specifically, the reference is supplied to teach the desirability of the purification process: that purified antibodies are commercially desirable, which as applicant has pointed out, the reference clearly sets forth.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

December 30, 2001

